K083545

Section 7 - 510(k) Summary

The following information is being submitted in accordance with the requirements of 21 CFR §807.92

Date: April 30, 2009

MAY 15 2009

Name of Submitter:

Ziehm Imaging, Inc.
4181 Latham Street
Riverside, CA 92501
(951) 718-2020

Contact Person:

Richard L. Westrich
Vice President of Regulatory Affairs and Quality Assurance
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Riverside, CA 92501
Office phone: +951-781-2020 ext 140
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Device Proprietary Name:

Ziehm Vision RFD

Classification Name:

Regulation Description: System, X-Ray, Fluoroscopic, Image Intensifier,

Product Code: JAA	Regulation number: 892.1650
Subsequent Product Code: MQB	Regulation number: 892.1650

Common/Usual Names:

Digital Mobile C-Arm
Mobile Surgical C-Arm
Mobile C-Arm

Substantial Equivalence:

The ZIEHM VISION RFD mobile c-arm has been found to be substantially equivalent to the following current legally marketed devises.

- Ziehm Imaging, ZIEHM VISION R K061203 Product Code JAA & IZL
- Ziehm Imaging, ZIEHM VISION^2 FD K073346 Product Code JAA, MQB & IZL

These devices are mobile C-arm type x-ray systems intended for fluoroscopic imaging. The systems include high-voltage x-ray generator, and can control, fixed anode and rotating x-ray tubes, Flat-panel Detector SSXI, or Image Intensifier, and monitor cart/workstations with video image displays, digital image processing and image storage capability, as well as image export functionality.

Device Description:

Indications for Use

The ZIEHM VISION RFD is intended for use in providing medical imaging, using pulsed and continuous fluoroscopic digital imaging, as well as digital subtraction and cine image capture during diagnostic interventional, and surgical procedures where intra-operative imaging and visualization of complex anatomical structures of both lower and higher contrast density are required, such procedures may included but are not limited to those of interventional cardiology, heart surgery, hybrid procedures, interventional radiology, interventional angiography, electrophysiology, pediatrics, endoscopic, urological, gastroenterology, orthopedic, maxillofacial surgery, neurology, neurosurgery, critical care, emergency room procedures, and those procedures visualizing structures of the cervical, thoracic, and lumber regions of the spine and joint fractures of the upper and lower extremities, and where digital image data is required for computer aided surgery procedures and whenever the clinician benefits from the high degree of geometric imaging accuracy, and where such fluoroscopic, cine and DSA imaging is required in and around high magnetic fields. The visualization of such anatomical structures assists the clinician in the clinical outcome. At the discretion of a physician the device may be used for other imaging applications.

This device does not support direct radiographic film exposures and is not intended for use in performing mammography.

User Characteristics

The ZIEHM VISION RFD does not require nor is it intended to be used in contact with patients. In some circumstances however, as part of its use in clinical environments the patient may come in contact with the device when operator moves or positions the device. The device is intended for use by health care professionals such as but not limited to physicians, orthopedic surgeons, vascular surgeons, neuro-vascular surgeons, cardiologists, radiologists, or other clinical physicians and technologists in hospitals, emergency rooms, out-patient clinics, and other clinical environments. Ziehm Imaging anticipates the device will be used on a nearly daily basis. Ziehm Imaging applications specialists and/or qualified site personnel provide on site operator training in the proper use of the device.

General Description

The ZIEHM VISION RFD Mobile Stand incorporates a small compact design making the positioning of the c-arm in relation to the patient easier for the operator. The C-profile provides fixed distance mounting of the generator and Flat-panel Detector (SSXI) and manual rotation around a non iso-centric location. The mobile stand allows manual rotational and linear movements with a motorized vertical movement for positioning the c-arm at various angles and distances for visualization of patient's anatomical structures. The high frequency generator with dual focus rotating anode x-ray tube, advanced active cooling, x-ray control, are assembled in one housing in a single mono-block generator tube housing assembly, with the virtual collimator mounting to the housing assemble. The Ziehm Vision RFD can have one of the following two generators 7.5 kW or optional 20 kW. They both provide pulsed and continuous fluoroscopy operations including a special digital radiography (snapshot) mode. The VisionCenter is a centralized touch screen panel providing the user/operator with a clear graphical user Interface including the x-ray control panel. The ZIEHM VISION RFD Monitor Cart workstation consists of a mechanical cart assembly, supporting dual high-resolution flat panel LCD display monitors and interfaces are provided for preipherial devices such as external monitors, video printers, injectors and storage devices (USB, DVD).

Standards:

The ZIEHM VISION RFD mobile x-ray devices shall be tested and be shown to meet the appropriate requirements of the following standards prior to being marketed.

21 CFR 1020.30-32	Federal Performance Standard for Diagnostic X-ray Systems
93/42/EEC -	Annex II of EC directive of the Medical Devices Directive (MDD)
IEC 60601-1,	Medical Electrical Equipment, General Requirements for Safety
IEC 60601-1-2	Medical Electrical Equipment, General Requirements for Safety, Electromagnetic Compatibility
IEC 60601-1-3,	Medical Electrical Equipment, Radiation Protection in Diagnostic X-ray Equipment
IEC 60601-1-4,	General requirements for safety, Programmable electrical medical systems.
IEC 60601-2-7,	Medical Electrical Equipment, Safety of HV/X-ray Generators
IEC 60601-2-28	Medical Electrical Equipment Part 2: Particular Requirements for the Safety of X-Ray Source Assemblies and X-Ray Tube Assemblies for Medical Diagnosis
IEC 60601-2-32,	Medical Electrical Equipment, Safety of Associated X-ray Equipment
IEC60601-2-43,	Particular requirements for the safety of X-Ray equipment for interventional procedures.
IEC 60825-1,	Safety of laser products, Equipment Safety, requirements, and user guide
IEC 14971	Risk Management

Conclusion:

The ZIEHM VISION RFD does not raise new questions of safety or effectiveness and is substantially equivalent to the currently marketed devices Ziehm Vision^2 FD (K073346) and Ziehm Vision R (K061203)

End of 510(k) Summary

Richard L. Westrich
Vice President Regulatory Affairs and Quality Assurance
Ziehm Imaging, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

JUL 30 2012

Mr. Richard Westrich
V. P. Regulatory Affairs and Quality Assurance
Ziehm Imagine, Inc.
4181 Latham Street
RIVERSIDE CA 92501

Re: K083545
Trade/Device Name: ZIEHM VISION RFD
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: OWB and JAA
Dated: March 25, 2009
Received: April 6, 2009

Dear Mr. Westrich:

This letter corrects our substantially equivalent letter of May 15, 2009.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

ziehm imaging

Indications for Use Statement

Applicant: Zichm Imaging, Inc.

510(k) Number (if known): K083545

Device Name: ZIEHM VISION RFD

Indications for Use:

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Prescription Use _X_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K083545